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and a second irradiance in a second wavelength range including 300nm to 400nm, said first irradiance being at least 20 W/cm² on the area to be irradiated and said second irradiance being less than 21% of said first irradiance on the area to be irradiated, such that the subject receives an irradiation dose within the range including 10 J/cm² to 200J/cm² from said first irradiance.

REMARKS

This preliminary amendment is presented to place the application in proper form for examination and to eliminate multiple dependency from the present claims. No new matter has been added. Early examination and favorable consideration of the above-identified application is earnestly solicited.

Any additional fees or charges required at this time in connection with the application may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted, COHEN, PONTANI, LIEBERMAN & PAVANE

v:

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VERSION WITH MARKINGS SHOWING CHANGES

In the Specification:

On Page 5, after line 1, insert the following heading:

--BACKGROUND OF THE INVENTION

1. Field of the Invention--;

On page 5, after line 3, insert the following heading:

--2. Description of the Prior Art--

On page 7, after line 1, insert the following heading:

--3. Summary of the Invention--;

On page 7, replace the paragraphs beginning on lines 2 and 6 with the following:

[Therefore, the invention is based on the technical problem of providing] An object of the present invention is to provide an irradiation device for treating primary T cell mediated skin disorders which has fewer side effects than the prior art devices and in particular is also suitable for treating children.

[The solution to the technical object emerges from the features of patent claim 1] The object according to the present invention is met by an irradiation device for therapeutic and cosmetic purposes, including at least one optical radiation source which generates a first irradiance of at least 20 mW/cm² in the wavelength range of 400 to 440 and generates a second irradiance in the wavelength range of 300-400 of less than 21% of the first irradiance. The surprising activity of the radiation on the T cells in the range from 400 - 440 nm has made it possible to create an irradiation device for the treatment of primary T cell mediated skin disorders which on the one hand makes it possible to treat skin disorders which it has scarcely

been possible to treat previously, such as lichen ruber, and on the other hand, since the carcinogenicity is lower by powers of 10 compared to UVA, also allows children to be treated. Its efficacy has already been impressively confirmed in clinical trials. In these trials, the test subjects were treated with irradiation doses of between 10 and 200 [joules] joules/cm², a preferred irradiation dose being 50 [J] J/cm² in the wavelength range from 400 - 440 nm. Therefore, a further surprising effect is that a therapeutic effect is established even at 8% compared to the irradiation doses which have previously be prescribed. Consequently, it is possible to achieve lower irradiances, on the one hand, and shorter treatment times, on the other hand. Furthermore, it has been found that, unlike the 15 appointments which were previously required, even 3-5 days of treatment are sufficient, and according to information given by the patients a noticeable improvement occurred even after the first treatment. The area of the patient which is to be irradiated is at a distance of between 0.2 and 3 m from the irradiation device.

On page 8, replace the paragraph beginning on line 23, with the following:

With an administered radiation dose of 50 [J] <u>J/cm²</u> in the wavelength range from 400 - 440 nm, the radiation dose in the UVB range fluctuated between 25 - 150 [mJ] <u>mJ/cm²</u>. Despite these fluctuation bands, the UVB doses administered as a result lie considerably below the radiation doses from conventional UVB therapeutic techniques, which use starting doses of 200 mJ and increase to 800 [mJ] <u>mJ/cm²</u> over the course of several weeks of treatment. The same applies, to a much greater extent, for the UVA ranges around 364 nm. However, it is impossible to rule out the possibility of small proportions of the UVB range around 313 nm having a synergistic effect on therapy in the wavelength range from 400 - 440

nm. This is currently the subject of further clinical trials, in which the effect and, if appropriate, thresholds for the irradiance and/or

radiation dose for the 313 nm wavelength are to be determined. The same applies in a corresponding way to the UVA elements, although a synergistic effect can most likely be ruled out in this case.

On page 11, before the line 1, insert the following heading:

--BRIEF DESCRIPTION OF THE DRAWINGS--;

On page 11, before the line 28, insert the following heading:

--DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS--;

On page 13, replace the paragraph starting on line 27, with the following:

In addition, the casing tube 6 may be coated, on its inner side, with the phosphors which are known from low-pressure discharge lamps, in order in this way to transform additional components of the UVC radiation emitted by mercury into the wavelength range of 400 - 440 nm which is of interest. Since the phosphor itself has only low absorption in the range from 400 - 440 nm, it is in this way possible to effectively increase the emission in this wavelength range. A precondition for the use of blue phosphors in the evacuated casing tube, which may be filled with inert gas, is that the phosphor be cooled. Under normal operating conditions without cooling, the casing tube reaches up to 600°C. However, the efficiency of the bluephosphors drops greatly at temperatures above 100°C, so that they can only usefully be

employed if the temperature is controlled at below 100°C, as can be achieved by means of the coolant unit described above. By using phosphors in combination with other dopants which preferably emit in the UV range in the quartz burner, it is possible to further increase the efficiency of the optical radiation source. Halide compounds of the metals selenium, antimony, zinc and cadmium are suitable for this purpose. Phosphors which may be used to coat the inside of the casing tube 6 include Sr₂P₂O₇:EU, (SrMg)₂P₂O₇:Eu, Sr₃Cl(PO₄)₃:Eu, BaMg₂Al₁₈O₂₇:Eu, SrMgAl₁₈O₅₀:Eu, BaMg₂Al₁₆:Eu:Mn, Sr₃(PO₄)₂:Eu, Ba₃(PO₄)₂:Eu, CaWO₄:Pb and CaWO₄.

In the Abstract:

Amend the abstract as follows:

[The invention relates to an] An irradiation device for therapeutic and cosmetic purposes [for] including the treatment of primary T cell mediated skin disorders, in particular of atopic dermatitis (neurodermatitis), cutaneous T cell lymphoma, lichen ruber, alopecia areata, systemic lupus erythemetodes and psoriasis and for cosmetic tanning, [comprising] has at least one optical radiation source which, on an area to be irradiated, generates an irradiance in the wavelength range from 400 - 440 nm [generates an irradiance] of at least 2 mW/cm² and generates an irradiance in the wavelength range from 300 - 400 nm [generates an irradiance] of less than 21% of the irradiance in the wavelength range from 400 - 440 nm.

[(Fig. 2)]

In the Claims:

Please amend the amended version of claim 1 (as amended on August 4, 2000 in the international phase) and original claims 2-14 and add new claim 15 as follows:

- applications for the treatment of primary T cell mediated skin disorders[, in particular of] including atopic dermatitis (neurodermatitis), cutaneous T cell lymphoma, lichen ruber, alopecia areata, systemic lupus erythemetodes and psoriasis and cosmetic applications including [for] cosmetic tanning, wherein [the] said irradiation device comprises at least one optical radiation source which, on an area to be irradiated, is operatively arranged for generating an irradiance in [the] a first wavelength range including 400nm to 440nm [from 400 440 nm generates an irradiance] of at least 20 mW/cm² and generating an irradiance in [the] a second wavelength range including 300nm to 400nm [from 300 400 nm generates an irradiance] of less than 21% of the irradiance in the first wavelength range [from 400 440 nm].
- 2. (Amended) The irradiation device [as claimed in] of claim 1, wherein [the] said optical radiation source is [designed as] a mercury low-pressure discharge lamp comprising a phosphor selected from the group consisting of [one of the following phosphors] $Sr_2P_2O_7$:EU, $(SrMg)_2P_2O_7$:Eu, $Sr_5Cl(PO_4)_3$:Eu, $BaMg_2Al_{18}O_{27}$:Eu, $SrMgAl_{18}O_{50}$:Eu, $BaMg_2Al_{16}$:Eu:Mn, $Sr_3(PO_4)_2$:Eu, $Ba_3(PO_4)_2$:Eu, $CaWO_4$:Pb [or] and $CaWO_4$.

- 3. (Amended) The irradiation device [as claimed in] of claim 1, wherein [the] said optical radiation source is [designed as] a metal halide lamp having a firing gas, [and] mercury and [having] at least one metal halide additive [additives] selected from the group consisting of gallium indium iodide, gallium iodide, selenium, antimony, zinc [and/or] and cadmium.
- 4. (Amended) The irradiation device [as claimed in] of claim 3, wherein [the] a weight ratio between [the] said mercury and [the] said at least one metal halide additive is 10:100.
- 5. (Amended) The irradiation device [as claimed in one of the preceding claims] of claim

 1, wherein said optical radiation source comprises a [the] discharge [tube] lamp including two electrodes arranged in a quartz tube, wherein electrode regions of said discharge lamp proximate said two electrodes [in an electrode region (8) is made] comprise zirconium oxide, thereby exhibiting a partially reflective [by means of zirconium oxide] characteristic.
- 6. (Amended) The irradiation device [as claimed in one of the preceding claims] of claim 1, further comprising one of [wherein between the optical radiation source and the surface to be irradiated there is] a glass pane as a UVB filter [or] and a transparent, UV-opaque plastic[, in particular GS acrylic or polycarbonate,] as a UV filter arranged between said optical radiation source and the surface to be irradiated.

- 7. (Amended) The irradiation device [as claimed in] of claim [6] 1, [wherein] further comprising a [the] UVB filter [is designed as] comprising an evacuated casing tube [(6)] arranged around [the] said optical radiation source, wherein said evacuated casing tube comprises a glass pane.
- 8. (Amended) The irradiation device [as claimed in] of claim 7, wherein [the] an inner side of the casing tube [(6)] is coated with a phosphor [as set forth in claim 2] selected from the group consisting of Sr₂P₂O₂:EU, (SrMg)₂P₂O₂:Eu, Sr₅Cl(PO₄)₃:Eu, BaMg₂Al₁₈O₂₇:Eu, SrMgAl₁₈O₅₀:Eu, BaMg₂Al₁₆:Eu:Mn, Sr₃(PO₄)₂:Eu, Ba₃(PO₄)₂:Eu, CaWO₄:Pb and CaWO₄.
- 9. (Amended) The irradiation device [as claimed in] of claim 1, wherein [the] said optical radiation source [is designed as] includes an electrode-free mercury metal halide lamp [which is] comprising a quartz bulb filled with at least one dopant selected from the group consisting of gallium, gallium iodide, gallium bromide [and/or] and gallium chloride [and which is assigned], said optical radiation source further comprising a resonator formed by a metallic shield and at least one magnetron [(18)] with an antenna [(19), by means of which] operatively arranged for introducing electromagnetic energy [can be introduced into a] into said resonator [which is formed by a metallic shield (20) and in which a quartz bulb (2) which contains the dopants is arranged].
- 10. (Amended) The irradiation device [as claimed in] of claim 9, wherein [the] said resonator is [designed as] an E_{01} mode resonator for the electromagnetic radiation introduced by [the] said magnetron [(18)].

- 11. (Amended) The irradiation device [as claimed in one of the preceding claims] of claim 1, [wherein the irradiation device is designed with] further comprising an IR filter.
- 12. (Amended) The irradiation device [as claimed in one of the preceding claims] of claim 1, [wherein the irradiation device is assigned] further comprising a cooling unit.
- 13. (Amended) The irradiation device [as claimed in] of claim 12, wherein [the] said cooling unit [is designed as] comprises a transparent casing tube [(11)] with an inlet [(12)] and an outlet [(13)], [which is] said transparent casing tube being arranged around [the] said optical radiation source, and an IR-absorbent coolant [(17) being] is circulated via [the] said inlet [(12)] and said outlet (13).
- 14. (Amended) The irradiation device [as claimed in] of claim 13, wherein [the] said coolant [(17) is] comprises one of water [or] and silicone oil.